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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,277	12/15/2006	Catherine Clelland	02420/100M850-US1	8267
7278	7590	10/23/2009	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			STAPLES, MARK	
			ART UNIT	PAPER NUMBER
			1637	
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			10/23/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/558,277	<b>Applicant(s)</b> CLELLAND ET AL.	
	<b>Examiner</b> MARK STAPLES	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-10,12,13,15,16,25,39,40,42-50,64,65,78,79,85,86 and 88 is/are pending in the application.
- 4a) Of the above claim(s) 55,56,90,93,97 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-10,12,13,15,16,25,39,40,42-50,64,65,78,79,85,86 and 88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/25/2005, 02/09/2006, &amp; 03/01/2006</u> .                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of claims 1, 2, 6-10, 12, 13, 15, 16, 25, 39, 40, 42-50, 86, and 88 of Group I in the reply filed on 09/16/2009 is acknowledged. The traversal is on the ground(s) that there is no serious search burden to examine all of the claims as a search for one Group would be coextensive with the other and there unifying technical features. This is not found persuasive because there is no special technical feature linking the claims under PCT Rule 13.2.

The requirement is still deemed proper and is therefore made FINAL.

As claims 85 and 86 are dependent from claim 64 of Group III, claims 64, 65, 78, 79, 85 and 88 of Group III will be examined with Group I claims.

2. Claims 55, 56, 90, 93, 97, and 104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/16/2009.

In summary, claims 1, 2, 6-10, 12, 13, 15, 16, 25, 39, 40, 42-50, 64, 65, 78, 79, 85, 86, and 88 as filed on 12/15/2006 will be fully examined for patentability.

***Drawings***

3. New corrected drawings of Figure 6 in compliance with 37 CFR 1.121(d) are required in this application because the axis labels and the legend text are not legible in Figure 6. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Specification***

4. The use of the trademark BLACK HOLE QUENCHER™ has been noted in this application. It and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to scan the entire application to ensure trademark usage in all the places where it appears in the application is in compliance with the current office guidelines.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 6-10, 39, 40, and 42-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ralph et al. (US Patent No. 6,190,857 issued 2001).

Regarding claims 1, 2, 43, and 44, Ralph teaches methods for evaluating a physical state of a subject (see abstract) which method comprises comparing (i) an expression profile of surrogate cells from the subject (see column 5, lines 33-43 and see example 5), with (ii) a normal expression profile of surrogate cells from a normal subject or subjects (see column 5, lines 33-43 and example 5), wherein a difference between the expression profiles is indicative of the physical state of the subject under investigation (see column 5, lines 33-60 and example 5). Ralph also teaches treatment with gene therapy vectors and antisense (see columns 23 and 24).

With regard to claim 6, Ralph teaches human subjects (see column 89, lines 30-67, for example).

With regard to claims 7 and 8, Ralph teaches the use of peripheral blood leukocytes encompassing monocytes, macrophages, etc. (see column 89, lines 30-67).

With regard to claims 9, 10, and 25, Ralph teaches detection of breast and prostate cancer (see column 89, lines 28-30 and example 5).

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With regard to claims and 45-50, Ralph teaches diagnosis and prognosis and monitoring therapies using the method (see column 5, lines 44-47). Ralph also teaches analysis of risk or susceptibility to disease (see column 5, lines 3-7). Ralph further teaches testing a biochemical marker of the physical state in blood (see column 89, example 5). In addition, Ralph teaches biopsy as a comparison (see column 89, lines 59-61).

With regard to claims 39 and 40, Ralph teaches cDNA on nylon membranes which represents a cDNA microarray (see column 16, lines 29-50).

With regard to claim 42, Ralph teaches RT-PCR (see column 54, lines 1-7).

7. Claims 1, 2, 6-8, 12, 13, 15, 16, 25, and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ilani et al. (2001).

Regarding claims 1, 2, 43, and 44, Ilani teaches a methods for evaluating a physical state of a subject (see abstract) which method comprises comparing (i) an expression profile of surrogate cells from the subject (see Figure 1 and p. 626), with (ii) a normal expression profile of surrogate cells from a normal subject or subjects (see Figure 1 and p. 626), wherein a difference between the expression profiles is indicative of the physical state of the subject under investigation (see Figure 1 and p. 626).

With regard to claim 6, Ilani teaches human subjects (see p. 626 column 1).

With regard to claims 7 and 8, Ilani teaches the use of peripheral blood leukocytes encompassing monocytes, macrophages, etc. (see p. 626, column 1).

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With regard to claims 12, 13, 15, 16, and 25, Ilani teaches detection and evaluation of patients for schizophrenia and Alzheimers (see p. 626, Figure 1, and p. 628 column 1).

With regard to claims 45-50, Ilani teaches diagnosis and prognosis and monitoring therapies using the method (see p. 628, column 2). Ilani also teaches RT-PCR (see page 626, column 2).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 64, 65, 78, 79, 85, 86, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamizono et al (U.S. Patent 6,248,533 issued 2001), Ralph et al. (US Patent No. 6,190,857 issued 2001), and Ilani et al. (2001).

Regarding claim 64, Kamizono teaches a methods for identifying a nucleic acid containing a sequence alteration that results in susceptibility to a physical state (see abstract) comprising: (a) selecting a nucleic acid that has altered expression in a surrogate cell from a subject with the physical state when compared to a surrogate cell from a normal subject or subjects (see column 11, table 7 regarding IDDM patients) and (b) comparing the genomic sequence of the nucleic acid including the transcribed region, wherein a sequence difference indicates that the nucleic acid alteration results in or contributes to susceptibility to the physical state (see column 11, table 7 and example 11).

With regard to claim 65, Kamizono teaches linkage of the polymorphism to IDDM (see example 11 and table 7). Kamizano also teaches DNA analysis (see column 6, example 4)and human subjects (see column 12, example 11). Kamizano also teaches isolation from PBMC (see column 5, example 2). Kamizano also teaches the use of Biopsy specimens (see column 3, line 7).

With regard to claims 85, 86, and 88, Kamizano teaches diagnosis (see column 11, table 7 and abstract) and teaches a method of claims 1, 2, 43, and 44, for evaluating a physical state of a subject (see abstract) which method comprises comparing (i) an expression profile of surrogate cells from the subject (see column 5, lines 33-43 and see example 5), with (ii) a normal expression profile of surrogate cells from a normal



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subject or subjects (see column 5, lines 33-43 and example 5), wherein a the expression profiles is indicative of the physical state of the subject under investigation (see column 5, lines 33-60 and example 5).

Ralph teaches a method of claims 1, 2, 43, and 44, for evaluating a physical state of a subject (see abstract) which method comprises comparing (i) an expression profile of surrogate cells from the subject (see column 5, lines 33-43 and see example 5), with (ii) a normal expression profile of surrogate cells from a normal subject or subjects (see column 5, lines 33-43 and example 5), wherein a difference between the expression profiles is indicative of the physical state of the subject under investigation (see column 5, lines 33-60 and example 5). Ralph also teaches analysis of risk or susceptibility to disease (see column 5, lines 3-7).

With regard to claim 89-94, Ralph teaches treatment with gene therapy vectors and antisense (see columns 23 and 24).

Ralph teaches application to a variety of disease states but does not teach neurological disease states.

Ilani teaches a method of claims 1, 2, 43, and 44, for evaluating a physical state of a subject (see abstract) which method comprise comparing (i) an expression profde of surrogate cells from the subject (see figure 1 and page 626), with (ii) a normal expression profile of surrogate cells from a normal subject or subjects (see figure 1 and page 626), wherein a difference between the expression profiles is indicative of the physical state of the subject under investigation (see figure 1 and page 626).

With regard to claims 78 and 79, Ilani teaches detection and evaluation of patients for schizophrenia and Alzheimers (see p. 626, Figure 1, and p. 628 column 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the full scope of the Ralph method and the Ilani method in the method of Kamizano for therapeutic selection. The motivation to do so is provided by Kamizano who teaches that polymorphisms may be significantly associated with disease and the teaching of Ralph and Ilani of how to demonstrate disease associations. It would further have been obvious to apply the method of Kamizano to any disease known to be associated with surrogates as taught or suggested by Ralph and Ilani. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

11. No claim is free of the prior art.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/  
Examiner  
Art Unit 1637  
October 21, 2009